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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,706	01/23/2006	Shing Yue Chan	CU60405	7430

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
06/01/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Advisory Action ***Before the Filing of an Appeal Brief***	**Application No.** *10/565,706*	**Applicant(s)** CHAN ET AL.
	Examiner Isis Ghali	**Art Unit** 1611

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 09 May 2011 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-10,23,24 and 35-37*.
   Claim(s) withdrawn from consideration: *11-22,25-34 and 38-47*.

/Isis Ghali/
Primary Examiner, Art Unit 1611

U.S. Patent and Trademark Office
PTOL-303 (Rev. 08-06)**Advisory Action Before the Filing of an Appeal Brief** Part of Paper No. 20110523

Continuation of 3. NOTE: Claims 1-10, 23-24, 35-37 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (US 2003/0068376) in view of Lerner et al. (US 6,197,331), as evident by the article by Lamosa et al. ("Design of Microencapsulated Chitosan Microspheres for Colonic Drug Delivery").

Continuation of 5. Applicant's reply has overcome the following rejection(s): rejection of claims 8, 35 and 37 under 35 U.S.C. 103(a) as being unpatentable over the combination of Chen and Lender as evident by Lamosa and further in view of Adusumili et al. (US 2004/0037879).

Applicants argue that One-skilled in the art would not combine the cited references. Chen is directed to "an intraoral quick-dissolving film which is applied lingually. Chen does not teach the use of enteric polymers for its film. There is no suggestion in Chen that these water soluble components can or should be replaced with enteric polymers or that enteric polymers would produce the described quick-dissolving film. Lerner is directed to an oral patch that "adhere[s] to hard dental surfaces, such as teeth and dentures." The oral patch is designed to remain on the tooth or denture for a period of time and provide controlled or sustained release of pharmaceutical agents to the patent. Although Lerner refers to certain enteric Eudragit® polymers as suitable polymers for release layers and/or adhesive layers, there is no discussion of these polymers imparting "quick dissolving" characteristics on the oral patch. Lerner states that a significant advantage of its "oral patch" over films is that the oral patch provides for greater adhesion than films, resulting in treatment for longer periods of time. Therefore, no suggestion to combine Chen with Lerner.
In response to this argument, it is argued that the present claims are not directed to any method of application of the orally dissolvable film, rather directed to a product that dissolves in the oral cavity. Applicants themselves admit Chen is directed to "an intraoral quick-dissolving film which is applied lingually". Lingual and sublingual areas are part of the oral cavity. It is noted that the features upon which applicant relies (i.e., site of application and speed of dissolution of the film) is not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See In re Van Geuns, 988 F.2d 1181,26 USPQ2d 1057 (Fed. Cir. 1993). It is further noted that Chen suggested using polyacrylic acid polymers in paragraph 0059, and those can be replaced by enteric polyacrylic acid polymers taught by Lerner because Lender teaches that enteric polymers, specially neutral copolymer of methacrylic acid and acrylic acid esters are suitable for forming mucosal composition that is degradable in the oral cavity and is comfortable in the mouth thus provides the minimal possibility of being dislodged, and further suitable for applying pharmaceutical active agent to the oral cavity for oral release and buccal absorption to allow rapid systemic delivery of the released pharmaceutical. Therefore, motivation to use enteric polymers is oral dissolvable formulation is taught by Lerner and reasonable expectation to arrive to the present invention exists. Regarding applicant's argument concerning rapid-dissolution of the film taught by Chen, it is noted that applicants' claims do not recite any dissolution time of the film. The film taught by Chen is used for the same purpose as instantly claimed film. It is further argued that oral patch taught by Lerner reads on the present claimed orally dissolvable film, in absence of claiming any specific site of application. Lerner is relied upon, as applicants' admit, for teaching specific neutral copolymer of methacrylic acid and acrylic acid esters. Lerner teaches such polymer as being suitable for forming mucosal composition that is degradable in the oral cavity and is comfortable in the mouth thus provides the minimal possibility of being dislodged. Lerner teaches that such polymers are suitable for applying

pharmaceutical active agent to the oral cavity for oral release and buccal absorption to allow rapid systemic delivery of the released pharmaceutical. Sustained release patch as taught by Lerner does not prevent rapid onset of action of the released drugs in the oral cavity because of the nature of the mucosa and its rich blood supply, therefore the ultimate result obtained from Chen which is rapid action of the drug is also desired by Lerner, which is rapid delivery. There is motivation to replace the polyacrylic acid polymer of Chen with those of Lerner as well as reasonable expectation to arrive to the present invention as previously discussed. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See Exparte Obiaya, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).
Since the references suggest all the components of the instant claims, the properties of the instant composition would be an intrinsic property. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 596 F.2d 1019, 201 USPQ 658 (CCPA 1979). If the prior art meets the structure recited, the properties must be met or Applicant's claim is incomplete. This is in line with In re Spada, 15 USPQ 2d 1655 (1990) which holds that products of identical chemical composition cannot have mutually exclusive properties. It is not impressive absent a showing that the art tried and failed to solve the same problem notwithstanding its presumed knowledge of the references. See In re Wright, 569 F.2d 1124, 193 USPQ 332 (CCPA 1977). The discovery of a new action underlying a known process does not make it patentable. MEHL/Biophile, 192 F.3d at 1365, 52 U.S.P.Q.2d at 1303. Also, it is irrelevant that the prior art observers did not recognize the property or function of the disputed claim; if the prior art inherently possessed that characteristic, it anticipates. See Verdeegal Brothers, Inc. v. Union Oil Co. of Cal., 814 F.2d 628, 633, 2 U.S.P.Q.2d 1051, 1054 (Fed. Cir. 1987). This is believed to be applicable here because anticipation is the epitome of obviousness.

Applicants argue that Chen teaches salts of nicotine and not nicotine oil as claimed. Nicotine oil when combined with neutralized polymers overcome the problem of nicotine salts with pH. In response to this argument, it is argued that applicant failed to show unexpected results obtained from using nicotine oil versus nicotine salts. The present claims as well as the present examples in the specification use nicotine salt.